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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,704	06/05/2000	Ralph M. Steinman	600-1-081 CON	7559

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	12

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/586,704	Applicant(s) Steinman et al.
	Examiner Ron Schwadron, Ph.D.	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *22, 23, and 26-34* is/are pending in the application.

4a) Of the above, claim(s) *22, 23, 29, 30, and 32-34* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *26-28 and 31* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Newly submitted claims 32-35 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons.

The originally claimed invention is drawn to a vaccine classified in Class 424 subclass 184.1. The invention of claims 32-34 is drawn to a method of inducing an immune response classified in Class 514, subclass 885. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as immunopurification of antibodies which bind said molecule. Because these inventions are distinct for the reasons given above and the search required for Group I (claims 26-28,31) is not required for Group II (Claims 32-34) and Groups I and II have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 32-34 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Claims 26-28,31 are under consideration.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any
> person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 26-28 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants arguments have been

considered and deemed not persuasive.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed conjugate.

The instant claims recite use of an antiDEC antibody. The specification discloses an anti human DEC antibody and an anti murine DEC antibody. However, the claims would encompass use of anti DEC antibody which binds DEC from any species of animal. There are thousands of different species of mammals. However, the only antiDEC antibodies disclosed in the specification are those that bind human or mouse DEC. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, the specification has only provided antiDEC antibodies which bind human or murine DEC. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated:

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming

rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

Regarding applicants comments, in University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, the specification has only provided antiDEC antibodies which bind human or murine DEC. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated:

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that

make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

5. Claims 26-28 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants arguments have been considered and deemed not persuasive.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed conjugates

The instant claims recite use of a carbohydrate that binds DEC. However, there is no disclosure in the specification as to the identity of any carbohydrate that actually binds DEC. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, there is no disclosure in the specification as to the identity of any carbohydrate that binds DEC. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated:

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

Regarding applicants comments about the specification, pages 38-40, there is no disclosure in the specification as to the identity of any carbohydrate that actually binds DEC. The specification, pages 38-40 discloses "candidate carbohydrates" (eg. carbohydrates that could be tested to determine if they bind DEC), but does not disclose that said carbohydrates actually bind DEC. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

6. Claims 26-28,31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants arguments have been considered and deemed not persuasive.

Claim 26 is indefinite in the recitation of "dendritic and epithelial cell (DEC)" ligand. There is no actual definition of said term in the specification. It is suggested that this rejection could be addressed by addition of limitations describing the physical characteristics of said molecule (eg. molecular weight, etc.)

Regarding applicants comments, there is no actual definition of said term in the specification. The specification, page 16, lines 16-20 indicate a tissue distribution for DEC. This is not a definition of said term in a physical/chemical sense. Regarding, the specification, page 16, lines 26-28, said passage refers to DEC-205. The claims under consideration do not recite "DEC-205".

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 26-28,31 stand rejected under 35 U.S.C. 103(a) as obvious over Nemazee (US Patent 5,698,679) in view of Kraal et al. Applicants arguments have been considered and deemed not persuasive.

Nemazee teaches peptide/Ig fusion proteins wherein the Ig portion of the fusion protein binds an APC cell surface antigen (see abstract). Nemazee teaches that the peptide portion of the fusion protein is derived from a virus (see column 7, penultimate paragraph). Nemazee teaches that the antibody can bind to the surface of APCs including dendritic cells (see column 10, first complete paragraph). Nemazee teaches that the fusion protein in combination with a lymphokine can be used to immunize an animal (see column 21, second paragraph and column 22, second paragraph). The aforementioned fusion protein/ lymphokine composition is a vaccine. Nemazee does not teach use of antiDEC as the antibody which binds a dendritic cell surface antigen. Kraal et al. teach the antidendritic cell antibody NLDC-145 (see summary). NLDC-145 binds DEC (see specification, page 3). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Nemazee teaches viral antigen/Ig fusion proteins wherein the Ig portion of the fusion protein binds dendritic cells and Kraal et al. teach the antidendritic cell antibody NLDC-145. One of ordinary skill in the art would have been motivated to do the aforementioned because Nemazee teaches that such fusion proteins can be used to immunize animals against the antigen portion of the conjugate (see column 18, penultimate paragraph) and

Nemazee teaches that the Ig portion of the fusion protein binds dendritic cells.

Regarding applicants comments, Nemazee et al. teach that:
"The present invention includes a novel immunoglobulin fusion protein having at least two components:(1)a peptide precursor; and (2) an immunoglobulin molecule(as defined below) having a variable region capable of binding to an antigen on the surface of an antigen presenting cells." (Column 4, first incomplete paragraph).
Nemazee discloses that the antibody used binds an antigen on the APC surface. Nemazee does not disclose that said antibody need have any other particular functional property. Kraal et al. teach the antidendritic cell antibody NLDC-145 (see summary) which binds an antigen on the cell surface of an APC (eg. dendritic cell). NLDC-145 also binds DEC (see specification, page 3). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Nemazee teaches viral antigen/Ig fusion proteins wherein the Ig portion of the fusion protein binds dendritic cells and Kraal et al. teach the antidendritic cell antibody NLDC-145. One of ordinary skill in the art would have been motivated to do the aforementioned because Nemazee teaches that such fusion proteins can be used to immunize animals against the antigen portion of the conjugate (see column 18, penultimate paragraph) and Nemazee teaches that the Ig portion of the fusion protein binds dendritic cells. Regarding applicants comments about the physical properties of DEC, the claims recite a conjugate containing an antibody which binds DEC and Kraal et al. teach an antibody which binds DEC. The claims are not drawn to DEC, they are drawn to an antibody conjugate that binds DEC. Kraal et al. teach such an antibody. Regarding applicants comments about the age of the Kraal et al. reference, the M.P.E.P. (August 2001) section 2145 (page 2100-151) teaches that: "The mere age of the references is not persuasive of the unobviousness of the combination of their teachings, absent evidence that, not withstanding knowledge of the references, the art tried and failed to solve the problem." *In re Wright*, 569 F.2d 1124, 193 USPQ 332, 335 (CCPA 1977)". Regarding applicants comments about enablement of the invention taught by Nemazee, said invention is described in claims 1-27 of said patent wherein said claims are contained in an issued US Patent wherein said claims are presumed enabled in the absence of evidence to the contrary. Regarding applicants comments about the fusion protein disclosed in Nemazee, said fusion protein contains an antiAPC antibody fused to an

antigen. The fusion protein recited in the claims contains an antiAPC antibody (antiDEC), fused to an antigen. The antibody taught by Kraal et al. has all the properties of an antiDEC antibody because it is an antiDEC antibody. The mechanism of action of the claimed conjugate is not germane to the instant rejection because the instant rejection renders obvious a conjugate that is the same as the conjugate recited in the claimed invention (antiDEC antibody/antigen conjugate). Nemazee teaches that the fusion protein in combination with a lymphokine can be used to immunize an animal (see column 21, second paragraph and column 22, second paragraph). The aforementioned fusion protein/ lymphokine composition is a vaccine.

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the

examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600